60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20150019A **DATE:** 1 June 2016

PROTOCOL TITLE: "Technique development for a polytrauma model to study partial resuscitative endovascular balloon occlusion of the aorta (P-REBOA) in swine (*Sus scrofa*)."

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Major Lucas Neff

DEPARTMENT: General Surgery **PHONE #:** 423-5224

INITIAL APPROVAL DATE: 19 March 2015 **LAST TRIENNIAL REVISION DATE:** 10 March 2016

FUNDING SOURCE:

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	15	10	15

2. **PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

___ Training: Live Animal	___ Medical Readiness	___ Prolonged Restraint
___ Training: non-Live Animal	___ Health Promotion	___ Multiple Survival Surgery
___ Research: Survival (chronic)	___ Prevention	___ Behavioral Study
_X__ Research: non-Survival (acute)	___ Utilization Mgt.	___ Adjuvant Use
___ Other ( )	__X_ Other (Treatment)	___ Biohazard

3. **PROTOCOL PAIN CATEGORY (USDA):** (Check applicable) ___ C _X_ D ___ E

4. **PROTOCOL STATUS:**

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

_X_ Completed, all approved procedures/animal uses have been completed

5. **Previous Amendments:**
List all amendments made to the protocol.. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	19 March 2015	Personnel
2	15 May 2015	Personnel

3	6 January 2016	Procedures

6. **FUNDING STATUS:** Funding allocated: $88,725.00 Funds remaining: $ 0.00

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? _X_ Yes ___ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

Capt Anders Davidson-AI-Approved, Dr. Sarah Ashley Ferencz-AI- Approved

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

None.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

None.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

None.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

None.

10. **PUBLICATIONS / PRESENTATIONS:** (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

None.

11. **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

Yes. This protocol led to animal model development that has become used in multiple research studies at the CIF, benefiting military medical research and graduate medical education.

12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

See next page.

(PI / TC Signature)

7 June 2016
(Date)

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

Attachment 1
Defense Technical Information Center (DTIC) Abstract Submission
This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Introduction: A reproducible, lethal non-compressible torso hemorrhage (NCTH) model is of importance to civilian and military trauma research. Current large animal models fail to balance clinical applicability with standardization and internal validity. As such, large animal models of trauma vary widely in literature, limiting comparisons.
Methods: Yorkshire-cross swine were anesthetized, instrumented, and splenectomized. A simple liver tourniquet was applied prior to injury to prevent unregulated hemorrhage while creating a traumatic amputation of 30% of the liver. Release of the tourniquet and rapid abdominal closure following injury provided a standardized reference point for the onset and duration of uncontrolled hemorrhage. At the moment of death, the liver tourniquet was quickly reapplied to provide accurate quantification of intra-abdominal blood loss. Weight and volume of the resected and residual liver segments were measured. Hemodynamic parameters were recorded continuously throughout the experiment.
Results: This liver injury was rapidly and universally lethal (11.2±4.9 min). The volume of hemorrhage (35.8% ± 6% of total blood volume), and severity of uncontrolled hemorrhage (100% of animals deteriorated to a sustained MAP<35mmHg for 5 minutes) were consistent across all animals. Use of the tourniquet effectively halted pre- and post- procedure blood loss allowing for accurate quantification of amount of hemorrhage over a defined period. Additionally, the tourniquet facilitated the creation of a consistent liver resection weight by body weight ratio (0.0043 ±0.0003) and as a percentage of total liver resection volume (27% ± 2.2%).
Conclusion: This novel tourniquet-assisted NCTH model creates a standardized, reproducible, highly lethal, and clinically applicable injury in swine. Use of the tourniquet allowed for consistent liver injury and precise control over hemorrhage. Finally, this model ensured survival can be reliably used as an endpoint when studying the efficacy of aggressive resuscitative interventions for patients *in extremis*.
(291 words)

Grant Number:_____
From:_____
****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**